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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,696	01/28/2002	Roland Stoughton	9301-168-999	5433

7590 09/29/2004

JONES DAY  
222 EAST 41 ST STREET  
NEW YORK, NY 10017

EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/058,696	<b>Applicant(s)</b> STOUGHTON ET AL.	
	<b>Examiner</b> Ardin Marschel	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 14-27 and 43-94 is/are pending in the application.
- 4a) Of the above claim(s) 45-54, 61, and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-27, 43, 44, 55-60 and 63-94 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 14-27 and 43-94 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>(10/058,696)</u>  | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

Applicant's election of the Specie directed to a pharmacological agent perturbation (as in instant claim 43) and the Specie directed to *Homo sapien* (as in claim 59) in the reply filed on 6/21/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Thus, instant claims 14-27, 43, 44, 55-60, and 63-94 are under examination.

### FIRST LACK OF SCOPE OF ENABLEMENT

Claims 14, 15, 20-27, 43, 44, 55-60, 63-82, and 87-94 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling (subject also to the below lack of enablement issue) for error distribution statistic as formulated in instant claim 16, does not reasonably provide enablement for any generic error distribution statistic. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those

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in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

It is noted that the specification on pages 17-19 describes the formulation of a microarray experimental data analysis methodology utilizing a particular formulation therefore as set forth as well in claim 16. This formulation methodology includes computation of intensity or spot brightness as well as variances in side intensity or spot brightness which are reasonably deemed to be very microarray data analysis specific. No other error distribution statistic or intensity independent statistic methodology or formulation has been instantly set forth. Microarrays with commonly hundreds or thousands of data items corresponding to locations thereon for probing of one or more samples is well known and acknowledged in Biotechnology to both be complex and difficult to analyze as to what conclusion(s) that the data support. Statistics is also acknowledged to be complex field and requires specific formulation(s) in order to carry out any reasonable evaluation. Thus, in summary the enablement of the error distribution statistic requires specific and detailed formulation guidance. Generic claim limitations which go beyond such specific and detailed formulation guidance lacks predictable enablement and thus is not enabled.

## **SECOND LACK OF SCOPE OF ENABLEMENT**

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Claims 14-27, 43, 44, 55-60, and 63-94 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling (subject also to the above lack of enablement issue) for a rank based method of determining expression level probability as in instant claim 22 combined with methodology of instant claim 24, does not reasonably provide enablement for any generic rank based method for said determining. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

In the specification on page 17, the percentile ranking of expression data is set forth via the formulations of the combined formulas of instant claims 22 and 24. These

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formulations are clearly related via the calculations of the  $P_i$  product vs. the  $1 - P_i$  product in claims 22 and 24, respectively. These types of probability calculations are standard for products of the "I" data items as calculated in claims 22 and 24. No other guidance regarding a rank based method has been instantly set forth. Calculations of this type as instantly described in the specification on page 17 are utilized to characterize up-regulated genes vs. down-regulated genes but not other different characterizations are set forth. Microarrays with commonly hundreds or thousands of data items corresponding to locations thereon for probing of one or more samples is well known and acknowledged in Biotechnology to both be complex and difficult to analyze as to what conclusion(s) that the data support. Statistics related to probability calculations are also acknowledged to be complex field and requires specific formulation(s) in order to carry out any reasonable evaluation. Thus, in summary, the enablement of probability calculation in such a complex field requires specific and detailed formulation guidance. Generic claim limitations which go beyond such specific and detailed formulation guidance lacks predictable enablement and thus is not enabled.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is

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(571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 25, 2004

*Ardin H. Marschel 9/25/04*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER